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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/524,090

07/05/2006

Simon Michael West

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EXAMINER

HUANG, GIGI GEORGIANA

ART UNIT

PAPER NUMBER

1612

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/524,090	<b>Applicant(s)</b> WEST ET AL.	
	<b>Examiner</b> GIGI HUANG	<b>Art Unit</b> 1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 3-17, 19-23 and 25 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 18 and 24 is/are rejected.
- 7) ☒ Claim(s) 3-17 and 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/5/2006</u> .  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Status of Application***

1. Applicant has elected Group I in response to restriction requirement and elected the “tocopherol” species for the examination.

Due to restriction, based on election of Group I, claims 20-22 and 25 (Group II, and claim 23 (Group III), are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claims 1-19 and 24 are present for examination at this time.

### ***Specification***

2. The disclosure is objected to because of the following informalities: Claim 24 is drawn to a method comprising the step of incorporating the pharmaceutical or pharmacologically active compound in a carrier comprising an effective amount of one or more phosphate derivative of a lipophilic pharmaceutically acceptable compound. The claim is not commensurate in scope with the disclosure. The disclosure supports to use of complexes of phosphate derivative in topical formulation to improve transdermal transport of ingredients, see page 4, paragraph 5 of the specification, but does not support the broad recitation of any phosphate derivative for the use.

Appropriate correction is required.

### ***Claim Objections***

3. Claims 3-17 and 19 are objected to under 37 CFR 1.75(c) as being in improper form because claim 3 is not in appropriate alternative form with the remaining claims in multiple dependent forms on multiple dependent claims 3-17 and 19. See MPEP

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§ 608.01(n). Accordingly, the claims 3-17 and 19 have not been further treated on the merits.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1, 2, 18, and 24 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The composition as recited in the above claims does not specify or give the possible phosphate derivatives of a lipophilic pharmaceutically acceptable compound. These are not described nor exemplified to provide adequate description for one of the art to know what is encompassed as the terms “derivative” and “complex” are indefinite and does not adequately describe the genus of compounds addressed. The specification also does not provide adequate written description of such compounds.

The claimed invention is drawn to a method for improving the efficacy and/or transdermal transport of topically administered pharmaceuticals and pharmacologically active compounds comprising incorporating one or more complexes of a phosphate derivative of a lipophilic pharmaceutically acceptable compound. Concise structural features that could distinguish structures of compounds within this genus from other are

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missing from the instant disclosure. The specification fails to teach or adequately describe a representative number of species in the broad genus such that the common attributes or characteristics concisely identifying members of the genus are disclosed, and because the claimed genus is so highly variant, the description provided is insufficient. There is a single representative species, laurylaminodipropionic acid tocopheryl phosphate utilized in the examples. A single species is not a representative number for an entire genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, Applicant was not in possession of the claimed genus.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 1, 2, 18, and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "derivative" is indefinite as it is unclear what is encompassed by the term and given the form any number of compounds given an infinite number of chemical reactions, the compounds can be anything and thereby it is unclear what is envisioned for the invention. It does not allow one of skill in the art to know the metes and bounds of the invention.

#### ***Claim Rejections - 35 USC § 102***

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1, 2, and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Oonishi et al. (U.S.Pat. No. 5965750).

Oonishi et al. teaches that tocopheryl phosphates and/or its salts exhibit antioxidant and blood circulation promoting effects (thereby increasing drug delivery through the skin when topically applied). The phosphates would also have excellent water solubility, be free from cutaneous irritation, allergenicity, and ensure dermal safety. Oonishi teaches that the phosphates and/or salt (complex) can be applied to sever applications including cosmetics and drugs. The purified form of tocopheryl phosphates would also contain a small amount of P,P'-bistocopheryl diphoshates (complex). Several examples comprising these phosphates are taught for topical administration with pharmacologically active components that would inherently have improved efficacy and/ transdermal transport due to improve stability (antioxidant properties) and increase blood circulation promoting effects (as increase circulation increases drug delivery across the dermal barrier). The examples taught include one or more phosphate derivatives (complexes), complexing agents (e.g. stearic acid), pharmacologically active components, and acceptable carriers. See examples B-9 (hair grower), examples B-15 (lotion), and B16 (cream). Note that the reference also teaches addition phosphate in Table I. (see full document, specifically, Abstract, Col. 6, lines 34-40, Col. 7, lines 45-59, Col. 22, lines 25-41, Col. 23, lines 10-27, Col. 50-65, Col. 26, lines 7-40)

All the critical elements are taught by the cited reference and thus the claims are anticipated.

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

11. Claims 1,2, and 24 are rejected under 35 U.S.C. 102(a) as being anticipated by West (WO 02/40033) or alternatively West et al (WO 02/40034).

West (WO 02/40033 , here after '034) teaches electron transfer agents comprising phosphate complexes of tocopherol, the usefulness of these compounds in therapeutic formulations due to their enhanced absorption properties (see full document, specifically Page 3, line 22-Page 4, line 2, Page 5, paragraph 3-Page 6, paragraph 5, Pages 7-9, Example 2, Table 1).

Alternatively, West et al. (WO 02/40034) teaches complexes of tocopherol phosphate and the usefulness of these compounds in therapeutic formulations and their enhanced absorption properties (Page 10, Paragraph2, Example 25, Page 31-34, claims).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1,2, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by West (WO 02/40033) or alternatively West et al (WO 02/40034).

West (WO 02/40033 , here after '034) teaches electron transfer agents comprising phosphate complexes of tocopherol, the usefulness of these compounds in therapeutic formulations due to their enhanced absorption properties (see full document, specifically Page 3, line 22-Page 4, line 2, Page 5, paragraph 3-Page 6, paragraph 5, Pages 7-9, Example 2, Table 1).

Alternatively, West et al. (WO 02/40034) teaches complexes of tocopherol phosphate and the usefulness of these compounds in therapeutic formulations and their enhanced absorption properties (Page 10, Paragraph2, Example 25, Page 31-34, claims).

All the critical elements are taught by the cited reference and thus the claims are anticipated.

14. Claims 1,2, 18, and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by West et al. (U.S. Pat. Publication No. 2004/0253318).

West teaches the incorporation of electron transfer agents comprising phosphate complexes of tocopherol, the usefulness of these compounds in therapeutic formulations due to their enhanced absorption properties. West also teaches that tocopheryl phosphate has been shown to regulate phosphorylation of the membrane



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messenger or signal protein resulting in a steeper oxygen gradient and a thinner epidermis which would allow for greater dermal transport and enhanced dermal transport as the epidermis is thinner. (see full document, specifically Abstract, Page 3, paragraph 39, Page 4 paragraph 61, Page 6, paragraph 94-96, page 12, Example 4, paragraph 168).

The applied references above have a common inventor/inventors and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1, 2, and 24 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 12 of copending Application No. 10/498684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of the instant claim is broader than that of the copending application thereby encompassing the claim of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

### ***Conclusion***

16. Claims 1,2, 18, and24 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to GIGI HUANG whose telephone number is (571)272-9073. The examiner can normally be reached on Monday-Thursday 8:30AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Fredrick Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

GH

/Zohreh A Fay/  
Primary Examiner, Art Unit 1612